

Serial No. 09/626,127

In re: Garger et al.

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**REMARKS**

Applicant wishes to thank the Examiner for the careful and thorough consideration of the instant application to date.

**CLAIM AMENDMENT**

Applicant has amended claim 2 to recite that the invention is a recombinant expression construct that comprises a nucleotide sequence encoding a *lysosomal enzyme* and a promoter that regulates the expression of the nucleotide sequence in a plant cell. Support for this amendment can be found in the specification, as is set forth below.

The instant application claims priority to several earlier filed patent applications, as previously acknowledged by the Examiner, including the following selected applications:

**(Priority Case A):** US Application Number 07/219,279, filed July 15, 1998, entitled "SYNTHESIS OF AN ESTERASE OF LIPASE BY NON-CHROMOSOMAL TRANSFORMATION OF A HOST", (now abandoned); and

**(Priority Case B):** US Application Number 07/363,138 filed June 8, 1989, entitled "SYNTHESIS OF STEREOSPECIFIC ENZYME BY NON-CHROMOSOMAL TRANSFORMATION OF HOST" (now abandoned).

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The specifications of the above patent applications were incorporated by reference on page 1 of the instant application.

The specification of **Priority Case A** includes a description of constructs used in the synthesis of a lysosomal enzyme, such as lipase in plant cells, as recited in amended claim 2.

Examples 18 and 19 in **Priority Case B** set forth further aspects of a construct for production of a lysosomal enzyme, such as lipase in plant cells, as recited in amended claim 2.

Applicant includes selected copies of pages from A DICTIONARY OF GENETICS, published by Oxford University Press in 1985 (**ATTACHMENT A**) that include a definition of lysosome that includes lipase, confirming that lipase was classified as a lysosomal enzyme as early as 1985, well before the acknowledged priority date of the instant application.

Therefore, there is sufficient support in the record for the amended claim language since Applicant has provided, via incorporation by reference, detailed descriptions of constructs and methodology for the production of lysosomal enzymes such as lipase.

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The Examiner is invited to contact the undersigned if copies of either or both of the specifications and claims of **Priority Case A** and/or **Priority Case B** are needed. The undersigned can either fax or have hand delivered copies of either specification.

#### **REJECTION UNDER 35 USC § 102**

In the Office Action, claim 2 was rejected under 35 USC § 102(b) over the Goodman et al reference (US Patent No. 4,956,282). Since the Goodman et al. reference published two years after the priority date of the instant application, Applicant assumes that the rejection was intended to be under 35 USC § 102(e). Regardless, Applicant asserts that the amendment to claim 2 clearly overcomes the rejection since the Goodman et al. reference discloses and claims the expression of peptides in plant cells. As is well known, peptides are molecules characterized as being small stretches of linked amino acids, typically 20 amino acids or fewer. In contrast, polypeptides and proteins are larger assemblies or polymers of peptides. Lysosomal enzymes are proteins that have far greater molecular size and complexity than peptides. The Goodman et al. reference clearly does not teach, disclose or suggested the complex constructs required for expressing lysosomal enzymes such as lipase, which have a corresponding complexity and size.

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For these reasons and others, Applicant respectfully asserts that the amendments to claim 2 clearly distinguish the invention over the cited prior art and is now in condition for allowance.

Should the Examiner wish to contact the undersigned for any reason, please call Mr. John C. Robbins at 707-469-2313. Mr. John C. Robbins is a registered US Patent Agent, is an employee of Large Scale Biology Corporation, the assignee of the instant application, and as such has signatory authority to prosecute the instant application, as set forth in the MPEP 402, 37 CFR § 1.34(a) and 37 CFR § 3.71.

Accompanying this amendment is a statement under 37 CFR § 3.73 and a copy of the Assignment for the instant application (ATTACHMENT B) and a change in correspondence address. Applicant respectfully requests that all correspondence from the USPTO be directed to the undersigned at Large Scale Biology Corporation, Vacaville California.

Respectfully submitted,

By 

John C. Robbins  
Registration No. 34,706  
Large Scale Biology Corporation  
3333 Vaca Valley Parkway Suite 1000  
Vacaville CA 95688  
Telephone: 707-469-2313

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**MARKED-UP VERSION TO SHOW CHANGES MADE**

2. (Amended) A recombinant expression construct comprising a nucleotide sequence encoding a [protein of interest] lysosomal enzyme and a promoter that regulates the expression of the nucleotide sequence in a plant cell.

# A DICTIONARY OF GENETICS

Attachment A  
1 of 3

THIRD EDITION

**ROBERT C. KING**

PROFESSOR OF BIOLOGY  
NORTHWESTERN UNIVERSITY

**WILLIAM D. STANSFIELD**

PROFESSOR OF BIOLOGY  
CALIFORNIA POLYTECHNIC STATE UNIVERSITY

New York Oxford  
OXFORD UNIVERSITY PRESS  
1985

Attachment A  
2 of 3

Oxford University Press  
Oxford London New York Toronto  
Delhi Bombay Calcutta Madras Karachi  
Kuala Lumpur Singapore Hong Kong Tokyo  
Nairobi Dar es Salaam Cape Town  
Melbourne Auckland

and associated companies in  
Beirut Berlin Ibadan Mexico City Nicosia

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Published by Oxford University Press, Inc.,  
200 Madison Avenue, New York, New York 10016

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Library of Congress Cataloging in Publication Data

King, Robert C.

A dictionary of genetics.

Rev. ed. of: A dictionary of genetics / Robert C.  
King. 2nd ed., rev. 1974

I. Genetics—Dictionaries. I. Stansfield,  
William D., 1930— II. King, Robert C., 1928—  
Dictionary of genetics. III. Title.

QH427.K55 1985 575.1'0321 84-29575

ISBN 0-19-503494-5

ISBN 0-19-503495-3 (pbk.)

Printing (last digit): 9 8 7 6 5 4 3 2 1

## Attachment A

3 of 3

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**lysogenization** the experimental production of a lysogenic strain of bacteria by exposing sensitive bacteria to a temperate phage.

**lysogenized bacterium** a bacterium harboring an experimentally introduced, temperate phage.

**lysogeny** the phenomenon in which genetic material of a virus and its bacterial host are integrated.

**lysosomal diseases** hereditary diseases in man arising from a deficiency of enzymes located in lysosomes. Fabry, Gaucher, Niemann-Pick, Pompe, and Wolman diseases arise from lysosomal enzyme deficiencies.

**lysosome** a membrane-enclosed intracellular vesicle that acts as the primary component for intracellular digestion in all eukaryotes. Lysosomes are known to contain at least 50 acid hydrolases, including phosphatases, glycosidases, proteases, sulfatases, lipases, and nucleases. Collectively they can hydrolyze all classes of macromolecules.

**lysozyme** an enzyme digesting mucopolysaccharides. Lysozymes having a bacteriolytic action have been isolated from diverse sources (tears, egg white, etc.). An important lysozyme is the enzyme synthesized under the direction of a phage which digests the cell wall of the host from within and thus allows the escape of the phage progeny.

**lytic response** lysis following infection of a bacterium by a virulent phage, as opposed to lysogenic response (*q.v.*).

**lytic virus** a virus whose intracellular multiplication leads to lysis of the host cell.



Attachment B

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PTO/SB/96 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

**STATEMENT UNDER 37 CFR 3.73(b)**Applicant/Patent Owner: Garger, et al.Application No./Patent No.: 09/626,127 Filed/Issue Date: July 26, 2000Entitled: Production of Lysosomal Enzymes in Plants by Transient ExpressionLarge Scale Biology Corporation a corporation

(Name of Assignee)

(Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that it is:

1. ☒ the assignee of the entire right, title, and interest; or
2. ☐ an assignee of less than the entire right, title and interest.  
The extent (by, percentage) of its ownership interest is \_\_\_\_\_ %

in the patent application/patent identified above by virtue of either:

- A. ☒ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel \_\_\_\_\_, Frame \_\_\_\_\_, or for which a copy thereof is attached.

OR

- B. ☐ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as shown below:

1. From: \_\_\_\_\_ To: \_\_\_\_\_  
The document was recorded in the United States Patent and Trademark Office at Reel \_\_\_\_\_, Frame \_\_\_\_\_, or for which a copy thereof is attached.
2. From: \_\_\_\_\_ To: \_\_\_\_\_  
The document was recorded in the United States Patent and Trademark Office at Reel \_\_\_\_\_, Frame \_\_\_\_\_, or for which a copy thereof is attached.
3. From: \_\_\_\_\_ To: \_\_\_\_\_  
The document was recorded in the United States Patent and Trademark Office at Reel \_\_\_\_\_, Frame \_\_\_\_\_, or for which a copy thereof is attached.

[ ] Additional documents in the chain of title are listed on a supplemental sheet.

- [ ] Copies of assignments or other documents in the chain of title are attached.

[NOTE: A separate copy (i.e., the original assignment document or a true copy of the original document) must be submitted to Assignment Division in accordance with 37 CFR Part 3, if the assignment is to be recorded in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

August 2, 2002  
Date

John C. Robbins

Typed or printed name

[Signature]  
Signature

Patent Agent, Reg. No. 34,706

Title

Attachment B  
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ASSIGNMENT

**COPY**

WHEREAS, we, Stephen J. Garger, Thomas H. Turpen, and Monto H. Kumagai, being citizens of the United States of America, residing at 593 Cottonwood Street, Vacaville, CA 95688, 160 Santa Fe Court, Vacaville, CA 95688, and 809 Plum Lane, Davis, CA 95616, respectively, have made new and useful improvements in **Production of Lysosomal Enzymes in Plants by Transient Expression**, for which an application for Letters Patent of the United States was filed on **July 26, 2000** as Application No. **09/626,127**.

WHEREAS, **Large Scale Biology Corporation**, having a place of business at **3333 Vaca Valley Parkway, Vacaville, CA 95688**, and who, together with its successors and assigns ("Assignee") is desirous of acquiring the title, rights, benefits, and privileges hereinafter recited.

NOW, THEREFORE, for valuable consideration furnished by Assignee to us, receipt and sufficiency of which we hereby acknowledge, we hereby, without reservations:

1. Assign, transfer, and convey to Assignee the entire right, title, and interest in and to said application for Letters Patent of the United States, including all claims, if any, for infringement prior to the date of this assignment, the inventions and discoveries described therein, any and all other applications for Letters Patent on said inventions and discoveries in whatsoever countries, including all divisional, renewal, substitute, continuation, and Convention applications based in whole or in part upon said inventions or discoveries, or upon said applications, and any and all Letters Patent, reissues, and extensions of Letters Patent granted for said inventions and discoveries or upon said applications, and every priority right that is or may be predicated upon or arise from said inventions, said discoveries, said applications, and said Letters Patent.

2. Authorize Assignee to file patent applications in any or all countries for any or all of said inventions and discoveries in our name or in the name of Assignee or otherwise as Assignee may deem advisable, under the International Convention or otherwise.

## Attachment B

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3. Authorize and request the Commissioner of Patents and Trademarks of the United States of America and the empowered officials of all other governments to issue or transfer all said Letters Patent to Assignee, as assignee of the entire right, title, and interest therein or otherwise as Assignee may direct.

4. Warrant that we have not knowingly conveyed to others any right in said inventions, discoveries, applications, or patents or any license to use the same or to make, use, or sell anything embodying or utilizing any of said inventions or discoveries; and that we have good right to assign the same to Assignee without encumbrance.

5. Bind our heirs, legal representatives, and assigns, as well as ourselves, to do, upon Assignee's request and at Assignee's expense, but without additional consideration to us or them, all acts reasonably serving to assure that the said inventions and discoveries, the said patent applications, and the said Letters Patent shall be held and enjoyed by Assignee as fully and entirely as the same could have been held and enjoyed by us, our heirs, legal representatives, and assigns if this assignment had not been made; and particularly to execute and deliver to Assignee all lawful application documents including petitions, specifications, and oaths, and all assignments, disclaimers, and lawful affidavits in form and substance as may be requested by Assignee; to communicate to Assignee all facts known to us relating to said inventions and discoveries or the history thereof; to furnish Assignee with any and all documents, photographs, models, samples, and other physical exhibits in our control or in the control of our heirs, legal representatives, or assigns which may be useful for establishing the facts of our conception, disclosures, and reduction to practice of said inventions and discoveries; and to testify as to the same in any interference or other litigation.

## Attachment B

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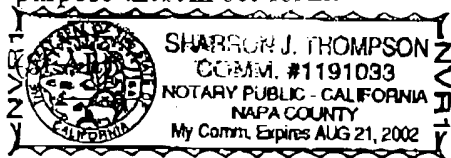
IN TESTIMONY WHEREOF, I have hereunto set my hand and seal this 28 day of  
November, 2000.

Stephen J. Garger  
Stephen J. Garger

STATE OF California  
COUNTY OF Solano

SS:

On this 28th day of November, 2000, before me personally appeared Stephen J. Garger, to me known and known to me to be the individual described in and who executed the foregoing instrument, and who duly acknowledged to me to have executed the foregoing instrument, and who duly acknowledged to me to have executed the same for the purpose therein set forth.



Sharon J. Thompson  
NOTARY PUBLIC

My Commission Expires: 8/21/02

## Attachment B

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IN TESTIMONY WHEREOF, I have hereunto set my hand and seal this 19th day of  
December, 2000.



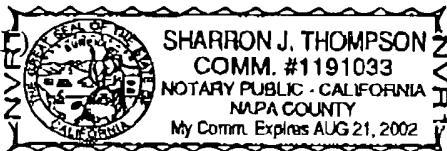
Thomas H. Turpen

STATE OF California  
COUNTY OF Solano

SS:

On this 19th day of December, 2000, before me personally appeared  
Thomas H. Turpen, to me known and known to me to be the individual described in and who  
executed the foregoing instrument, and who duly acknowledged to me to have executed the  
foregoing instrument, and who duly acknowledged to me to have executed the same for the  
purpose therein set forth.

(SEAL)



  
NOTARY PUBLIC

My Commission Expires: 8/21/02

## Attachment B

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IN TESTIMONY WHEREOF, I have hereunto set my hand and seal this 28 day ofNovember, 2000.

Monto H. Kumagai  
Monto H. Kumagai

STATE OF California  
COUNTY OF Solano

SS:

On this 28th day of November, 2000, before me personally appeared Monto H. Kumagai, to me known and known to me to be the individual described in and who executed the foregoing instrument, and who duly acknowledged to me to have executed the foregoing instrument, and who duly acknowledged to me to have executed the same for the purpose therein set forth.



Sharon J. Thompson  
NOTARY PUBLIC

My Commission Expires: 8/21/02